

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC. and  
QUEEN'S UNIVERSITY AT KINGSTON,

Plaintiffs,

v.

NEW ENGLAND COMPOUNDING  
PHARMACY, INC.,

Defendant.

Civil Action No. 04-12703 NMG

**NEW ENGLAND COMPOUNDING PHARMACY INC.'S ANSWER,  
COUNTERCLAIM AND JURY DEMAND**

Defendant New England Compounding Pharmacy, Inc. ("NECP") answers the Plaintiffs', DUSA Pharmaceuticals, Inc.'s and Queen's University at Kingston's (collectively "Plaintiffs") Complaint as follows:

**Jurisdiction and Parties**

1. NECP admits that the case purports to state two claims for inducement of patent infringement. NECP admits that this Court has jurisdiction of Plaintiffs' patent infringement claims under 28 U.S.C. §1331 and §1338(a). NECP does not contest venue in this district, but denies that it has committed any acts of infringement in this district, or any other district, that would substantiate Plaintiffs' purported patent infringement action and therefore to the extent DUSA relies on the allegation that NECP committed acts of infringement in this district in support of its claim that venue in this district is proper, NECP denies those allegations. NECP denies the remaining allegations contained in paragraph 1.

2. NECP is without knowledge or information sufficient to admit or deny the allegations contained in paragraph 2.

3. NECP is without knowledge or information sufficient to admit or deny the allegations contained in paragraph 3.

4. Admitted.

5. NECP admits that it conducts business and resides in this Commonwealth and Judicial District. Except as admitted, NECP denies the allegations contained in paragraph 5.

**Count I**

6. NECP admits that on its face U.S. Patent No. 6,710,066 (the “‘066 patent”) is entitled “Photochemotherapeutic Method Using 5-Aminolevulinic Acid and Other Precursors of Endogenous Porphyrins” and was issued by the United States Patent and Trademark Office on March 23, 2004. NECP further admits that the ‘066 patent states on its face that Queen’s University at Kingston is the assignee of the patent. NECP is without sufficient knowledge or information to admit or deny the remaining allegations contained in paragraph 6.

7. NECP is without sufficient knowledge or information to admit or deny the allegations contained in paragraph 7.

8. NECP admits that it compounds aminolevulinic acid solution for sale on a prescription basis. NECP admits that it had prepared on request a Patient Advisory Leaflet that is attached as part of Exhibits A and B to Plaintiffs’ Complaint. Except as admitted, NECP denies the allegations contained in paragraph 8, for reasons including, but not limited to, NECP had no knowledge of the ‘066 patent prior to engaging in any activities relating to the accused method.

9. NECP admits that for a period of time, now past, it sent to certain physicians part or all of the materials attached as Exhibit A to Plaintiffs’ Complaint. NECP also admits that it sent the facsimile attached as Exhibit B to Plaintiffs’ Complaint. Except as admitted, NECP denies the allegations contained in paragraph 9.

10. Denied.

**Count II**

11. NECP admits that on its face U.S. Patent No. 5,955,490 (the “‘490 patent”) is entitled “Photochemotherapeutic Method Using 5-Aminolevulinic Acid and Other Precursors of Endogenous Porphyrins” and was issued by the United States Patent and Trademark Office on September 21, 1999. NECP further admits that the ‘490 patent states on its face that Queen’s University at Kingston is the assignee of the patent. NECP is without sufficient knowledge or information to admit or deny the remaining allegations contained in paragraph 11.

12. NECP admits that it compounds aminolevulinic acid solution for sale on a prescription basis. NECP admits that for a period of time, now past, it sent to certain physicians part or all of the materials attached as Exhibit A to Plaintiffs’ Complaint. NECP also admits that it sent the facsimile attached as Exhibit B to Plaintiffs’ Complaint. Except as admitted, NECP denies the allegations contained in paragraph 12, for reasons including, but not limited to, NECP had no knowledge of the ‘490 patent prior to engaging in any activities relating to the accused method.

13. NECP admits that for a period of time, now past, it sent to certain physicians part or all of the materials attached as Exhibit A to Plaintiffs’ Complaint. NECP also admits that it sent the facsimile attached as Exhibit B to Plaintiffs’ Complaint. Except as admitted, NECP denies the allegations contained in paragraph 13.

14. Denied.

**First Affirmative Defense**

NECP does not induce infringement or infringe any valid and enforceable claim of the ‘066 or ‘490 patents.

**Second Affirmative Defense**

One or more claims of the '066 or '490 patents are invalid for failure to satisfy the conditions for patentability specified in 35 U.S.C. §101 *et seq.*, including without limitation the requirements in §§ 102, 103, and/or 112.

**Third Affirmative Defense**

The '066 and the '490 patents are unenforceable due to patent misuse because Plaintiffs' have attempted to impermissibly broaden the scope of their patent grants with anticompetitive effect.

**Fourth Affirmative Defense**

Plaintiff's claims must fail because NECP had no knowledge of the '066 patent nor the '490 patent prior to engaging in any activities relating to the accused method.

**Fifth Affirmative Defense**

Plaintiff's claims fail to state a claim pursuant to Federal Rule of Civil Procedure 12(B) (6).

**Sixth Affirmative Defense**

Plaintiffs' claims are barred by the Doctrine of Unclean Hands.

**Seventh Affirmative Defense**

NECP reserves all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the Patent Laws of the United States and any other defense, at law or in equity, that may now exist or in the future be available based on discovery and further investigation in this case.

**Defendant Demands A Jury Trial On All Issues So Triable.**

## **COUNTERCLAIMS**

### **Parties**

1. NECP is a corporation incorporated under the laws of the Commonwealth of Massachusetts, having a principal place of business at 697 Waverly Street, Framingham, MA 01702.

2. DUSA is a New Jersey corporation having its principal place of business at 25 Upton Drive, Wilmington, MA 01887.

### **Jurisdiction and Venue**

3. This court has jurisdiction over these counterclaims under 28 U.S.C. §1331 and §1367.

4. Venue is proper in this district pursuant to 28 U.S.C. §1391.

### **DUSA's Activities**

5. On December 27, 2004, DUSA issued a press release relating to the instant suit. (Exhibit A attached hereto)

6. The December 27, 2004 press release contained false and/or misleading remarks disparaging the quality and source of NECP's compounds of aminolevulinic acid ("ALA") solution.

7. On January 31, 2005, DUSA issued a press releasing announcing a suit against The Cosmetic Pharmacy of Tucson, Arizona for violations of the patent laws and of the Lanham Act for false advertising and trademark infringement, which repeated the contents of DUSA's December 27, 2004 press release. (Exhibit A)

8. The January 31, 2005 press release contained false and/or misleading statements disparaging the quality and source of NECP's compounds of ALA solution.

9. DUSA has also made false and/or misleading statements to NECP's customers and/or potential customers, disparaging NECP's business and the quality of NECP's products, including, but not limited to, incidents on or about February and March of 2005 at the South Shore Skin Care Center, and statements made to a physician during the winter of 2005 that it was illegal for the physician to purchase compounded medication from NECP.

10. DUSA has also made false and/or misleading statements to state and/or federal governing bodies disparaging NECP's business and the quality of NECP's products.

**Count I:**

**Tortious Interference With Advantageous Business Relationship**

11. NECP repeats and incorporates paragraphs 1-10 of its Counterclaims as if set forth fully herein.

12. Beneficial business relationships existed between NECP and certain physician-customers.

13. DUSA knew of the existence of such beneficial business relationships.

14. DUSA intentionally and maliciously interfered with those relationships by making false and/or misleading statements disparaging NECP's business and products.

15. DUSA's interference damaged and continues to damage NECP, including, but not limited to, damage to NECP from the loss of the benefits that may have resulted from the business relationships.

**Count II:**

**Violation of Mass. G.L. Chapter 93A, §11**

16. NECP repeats and incorporates paragraphs 1-15 of its Counterclaims as if set forth fully herein.

17. Both NECP and DUSA are engaged in trade or commerce within the meaning of Mass. Gen. L. c. 93A §§ 1(a), 1(b) and 11.

18. DUSA's actions as set forth above, including, but not limited to, DUSA's false and/or misleading disparagement of NECP's business and products, are unfair and deceptive acts within the meaning of Mass. G.L. Chapter 93A, §2(a) and §11. DUSA's actions occurred primarily and substantially within the Commonwealth of Massachusetts.

19. As a direct and proximate result of DUSA's unfair and deceptive acts, NECP has suffered and continues to suffer loss, including loss of business, goodwill and reputation.

20. On information and belief, DUSA's violations of Chapter 93A are knowing and willful, and NECP is entitled to treble damages and reasonable attorney's fees.

### **Count III**

#### **Lanham Act §43(a)**

21. NECP repeats and incorporates paragraphs 1-20 of its Counterclaims as if set forth fully herein.

22. DUSA made false and/or deceptive representations to customers, such as false and/or misleading remarks disparaging the quality and source of NECP's compounds comprising ALA solution.

23. DUSA's false and/or deceptive representations deceived a significant portion of the consuming public.

24. DUSA's conduct injured and continues to injure NECP, including injuries resulting from loss of business.

**Count IV**

**Defamation**

25. NECP repeats and incorporates paragraphs 1-24 of its Counterclaims as if set forth fully herein.

26. DUSA intentionally and recklessly made false and defamatory statements of fact regarding NECP's business and products to third parties.

27. DUSA's statements were not privileged.

28. DUSA's false statements damaged and continue to damage NECP's reputation and have harmed NECP through loss of business.

**Count V**

**Injurious Falsehood**

29. NECP repeats and incorporates paragraphs 1-28 of its Counterclaims as if set forth fully herein.

30. DUSA made false statements disparaging NECP's business and products.

31. DUSA maliciously made these statements knowing that they were false and/or with reckless disregard of whether they were false.

32. DUSA's actions harmed and continue to harm NECP, including harm to NECP through loss of business.



**NECP's Prayer for Relief**

NECP prays that this Court enter judgment as follows:

- (a) That NECP does not induce infringement and has not infringed any claim of the '066 patent and '490 patent, either literally or under the doctrine of equivalents;
- (b) That one or more claims of the '066 patent and '490 patent are invalid;
- (c) That the '066 and '490 patents are unenforceable;
- (d) That NECP is awarded damages for DUSA's actions against NECP;
- (e) That DUSA's violations of Chapter 93A are knowing and willful, and that NECP is entitled to treble damages and reasonable attorney's fees;
- (f) That Plaintiffs and all persons acting on their behalf or in concert with them are permanently enjoined and restrained from charging orally or in writing or otherwise publishing that the '066 patent or the '490 patent is infringed by any NECP product or that NECP induces infringement;
- (g) That plaintiff DUSA and all persons acting on its behalf or in concert with it are permanently enjoined and restrained from disparaging the quality and source of NECP's products;
- (h) That plaintiff DUSA and all persons acting on its behalf or in concert with it are permanently enjoined and restrained from making defamatory statements concerning NECP;
- (i) That NECP is awarded its costs and expenses in this action including interest;
- (j) That this case is exceptional and that NECP is awarded its attorney fees under 35 U.S.C. § 285 and/or Mass. Gen. L. c. 93A §11;
- (k) That judgment is entered against Plaintiffs, that Plaintiffs are denied all

their requested relief, and that this action is dismissed with prejudice; and

(l) That NECP is awarded such other and further relief as the Court deems appropriate.

**Defendant Demands A Jury Trial On All Issues So Triable.**

NEW ENGLAND COMPOUNDING  
PHARMACY, INC.

By its attorneys,

/s/ Daniel M. Rabinovitz

Daniel M. Rabinovitz, BBO No. 558419

Menard, Murphy & Walsh LLP

60 State Street - 34th Floor

Boston, Massachusetts 02109

(617) 832-2500

Dated: March 16, 2005

**CERTIFICATE OF SERVICE**

I, Daniel M. Rabinovitz, hereby certify that on this 16<sup>th</sup> day of March 2005, I caused a copy of this Answer and Counterclaim to be served by first-class mail, postage prepaid, addressed to Mona M. Patel, Esquire of Holland & Knight located at 10 St. James Avenue Boston, MA, 02116 and filed electronically on March 16, 2005

/s/ Daniel M. Rabinovitz

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# DUSA®

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DUSA Press Release

**DUSA Pharmaceuticals, Inc. ®**  
**For Immediate Release December 27,**  
**2004**

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## **DUSA PHARMACEUTICALS FILES SUIT AGAINST COMPOUNDING PHARMACY**

**Wilmington, MA. December 27th, 2004** - DUSA Pharmaceuticals, Inc. (NASDAQ: NMS:DUSA) reported today that it has filed a lawsuit against New England Compounding Center (NECC) of Framingham, Massachusetts alleging violations of U.S. patent law. The suit has been filed in the United States District Court in Boston, Massachusetts.

In addition, DUSA believes that certain actions of NECC go beyond the activities which are permitted under the Food, Drug and Cosmetic Act, and as a result, it has advised the U.S. Food and Drug Administration (FDA) and local health authorities of its concerns.

Dr. Geoffrey Shulman, DUSA's President and CEO, stated, "We have taken this action to protect our proprietary intellectual property position from pharmacies such as the NECC that are promoting and selling ALA of unknown quality from unknown sources. In addition, we intend to protect against damage to our product's reputation that might arise from the use of what could be an unsafe copy of our products. The recent serious incidents involving the use of non-FDA approved botulinum toxin illustrate how important it is to be proactive in this regard."

DUSA Pharmaceuticals, Inc. is a biopharmaceutical company engaged primarily in the development of Levulan Photodynamic Therapy (PDT) and Photodetection (PD) for multiple medical indications, with its primary focus in dermatology. PDT and PD utilize light-activated compounds such as Levulan to induce a therapeutic or detection effect. The Company maintains offices in Wilmington, MA, Valhalla, NY, and Toronto, Ontario.

Except for historical information, this news release contains certain forward-looking statements that involve known and unknown risk and uncertainties, which may cause actual results to differ materially from any future results, performance or achievements expressed or implied by the statements made. These forward-looking statements relate to the Company's belief regarding NECC activities and

its intention to protect its product's reputation and other risks identified in DUSA's SEC filings from time to time.

**For further information contact:**

**D. Geoffrey Shulman, MD**, President & CEO  
or Shari Lovell, Director, Shareholder Services Tel: 416.363.5059 Fax  
416.363.6602

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DUSA Press Release

**DUSA Pharmaceuticals, Inc. ®****For Immediate Release January 31, 2005****DUSA PHARMACEUTICALS FILES SUIT  
AGAINST SECOND COMPOUNDING PHARMACY**

**Wilmington, MA. January 31, 2005** - DUSA Pharmaceuticals, Inc. (NASDAQ NMS: DUSA) reported today that it has filed a lawsuit against The Cosmetic Pharmacy of Tucson, Arizona alleging violations of the Lanham Act for false advertising and trademark infringement, and of U.S. patent law. The suit has been filed in the United States District Court for the District of Arizona.

In addition, DUSA believes that certain actions of The Cosmetic Pharmacy go beyond the activities which are permitted under the Food, Drug and Cosmetic Act and as a result, it has advised the U.S. Food and Drug Administration (FDA) and Arizona State Board of Pharmacy of its concerns.

On December 27, 2004, DUSA announced that it had filed a lawsuit against New England Compounding Center of Framingham, Massachusetts alleging violations of U.S. patent law.

Dr. Geoffrey Shulman, DUSA's Chairman of the Board and Chief Executive Officer stated, "We are filing this second lawsuit to demonstrate that we intend to protect our proprietary intellectual property position from those compounding pharmacies that go beyond their legal limits and that are promoting and selling ALA of unknown quality from unknown sources. We have an obligation to protect against damage our product's reputation that might arise from the use of what could be an unsafe copy of our products. We intend to protect our trademarks and our goodwill, especially in light of recent events which implicate The Cosmetic Pharmacy in the recent serious incidents involving the use of non-FDA approved botulinum toxin, causing The Cosmetic Pharmacy to be restrained from committing violations of the Food Drug and Cosmetic Act by the United States District Court in the Southern District of Florida."

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